

JUSTICE NEWS

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Medtronic to Pay \$4.41 Million to Resolve Allegations that it Unlawfully Sold Medical Devices Manufactured Overseas

The Justice Department announced today that Medtronic plc and affiliated Medtronic companies, Medtronic Inc., Medtronic USA Inc., and Medtronic Sofamor Danek USA Inc., have agreed to pay \$4.41 million to the United States to resolve allegations that they violated the False Claims Act by making false statements to the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DoD) regarding the country of origin of certain Medtronic products sold to the United States.

“Today’s settlement demonstrates our commitment to ensure that our service members and our veterans receive medical products that are manufactured in the United States and other countries that trade fairly with us,” said Acting Assistant Attorney General Benjamin C. Mizer of the Justice Department’s Civil Division. “The Justice Department will take action to hold medical device companies to the terms of their government contracts.”

“Domestic manufacture is a required component of many military and Veterans Administration contracts,” said U.S. Attorney Andrew M. Luger of the District of Minnesota. “Congress has mandated that the United States use its purchasing power to buy goods made in the United States or in designated countries. We take that mandate seriously and will not hesitate to take appropriate legal action to ensure compliance.”

According to the settlement agreement, between 2007 and 2014, Medtronic sold to the VA and DoD products it certified would be made in the United States or other designated countries. The Trade Agreements Act of 1979 (TAA) generally requires companies selling products to the United States to manufacture them in the United States or in another designated country. The United States alleged that Medtronic sold to the United States products manufactured in China and Malaysia, which are prohibited countries under the TAA.

The specific Medtronic products at issue included anchoring sleeves sold with cardiac leads and used to secure the leads to patients, certain instruments and devices used in spine surgeries, and a handheld patient assistant used with a wireless cardiac device. The agreement covers the period from Jan. 1, 2007, to Dec. 31, 2013, and for one device (the handheld patient assistant), the period from Jan. 1, 2014, to Sept. 30, 2014.

The settlement resolves allegations originally brought in a lawsuit filed by three whistleblowers under the *qui tam* provisions of the False Claims Act, which allow private parties to bring suit on behalf of the government and share in any recovery. The relators will receive a total of \$749,700 of the recovered funds.

This settlement illustrates the government’s emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud

through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$23.9 billion through False Claims Act cases, with more than \$15.2 billion of that amount recovered in cases involving fraud against federal health care programs.

The case was handled by the U.S. Attorney's Office of the District of Minnesota with assistance from the Civil Division, DoD, Defense Logistics Agency and Defense Criminal Investigative Service and the VA's Office of General Counsel.

The underlying case is *United States of America ex rel. Samuel Adam Cox, III, Meayna Phanthavong, and Sonia Adams v. Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc.*, Civil No. 12-cv-2562 (PAM/JSM).

The claims resolved by the settlement are allegations only; there has been no determination of liability.

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Civil Division

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